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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,049	08/19/2003	David D. Cox	16011/103/105	5136

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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,049

Applicant(s)

COX ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' election, terminal disclaimers and request for extension of time, all filed 07/28/2005.

Response to Election/Restrictions

1. Applicant's election of Group I, claims 22-28 in the reply filed on 07/28/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claim 29 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 22-28 are included in the prosecution.

Terminal Disclaimer

3. The terminal disclaimer filed on 07/28/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of

U.S. Patent No. 5,829,442, U.S. Patent No. 6,216,699, U.S. Patent No. 6,503,531, and U.S. Patent No. 6,607,746 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

4. Claims 22-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/717,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the potentially conflicted claims are directed to composition comprising acrylic polymer and antimicrobial agent dispersed therein. It is an anticipatory double patenting rejection because the present claim anticipated at least claim 1 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

5. Applicant's arguments filed 07/28/2005 have been fully considered but they are not persuasive. Applicants state that no Terminal Disclaimer has been submitted with respect to co-pending Application Serial No. 10/717,380 since the copending application has not yet matured into a patent and, therefore, at present, cannot be the basis for a presently efficacious double patenting rejection.

In response to applicants' position, the examiner is pointing out to the fact that the "provisional" double patenting rejection should continue to be made by the examiner

in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only remaining rejection in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application into a double patenting rejection at the time one application issues as a patent. Therefore, the provisional double patenting rejection is maintained.

Claim Rejections - 35 USC § 112

6. Claims 22-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diiodomethyl-p-tolylsulfone as antimicrobial agent dispersed in acrylic polymer, does not reasonably provide enablement for all antimicrobial agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the

quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is a hot melt adhesive composition comprising diiodomethyl-p-tolylsulfone dispersed in acrylic polymer. The entire specification discloses diiodomethyl-p-tolylsulfone as antimicrobial agent. Nowhere in the specification applicants have disclosed any antimicrobial agent other than diiodomethyl-p-tolylsulfone.

The breadth of the claims: The claims are very broad. The claims encompass broad classes of antimicrobial agents that encompass antifungal, antiviral, antibacterial, antibiotics, etc.

The state of the prior art: The state of the art does not recognize hot melt adhesive composition comprising diiodomethyl-p-tolylsulfone dispersed acrylic polymer. The art recognized emulsion comprising acrylic polymer and diiodomethyl-p-tolylsulfone, US 5,500,470.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on antimicrobial agents other than diiodomethyl-p-tolylsulfone dispersed in the hot melt acrylic adhesive composition. It is not obvious from the disclosure of diiodomethyl-p-tolylsulfone dispersed in hot melt acrylic adhesive if the other antimicrobial agent will work and will stand the high temperature of the hot melt. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940),

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gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to hot melt adhesive composition comprising acrylic polymer and diiodomethyl-p-tolylsulfone dispersed in there makes practicing the claimed invention unpredictable in the terms of using other antimicrobial agents that may be heat sensitive.

The presence or absence of working examples: The specification discloses only diiodomethyl-p-tolylsulfone dispersed in heat melted acrylic adhesive. No working examples to show using other antimicrobial agents in hot melt adhesive comprising acrylic polymer. Therefore, the specification has enabled diiodomethyl-p-tolylsulfone dispersed in hot melt of acrylic polymer.

The quantity of experimentation necessary: The art demonstrates diiodomethyl-p-tolylsulfone dispersed in emulsion of mixture of acrylic polymers.

Therefor, the practitioner would turn to trial and error experimentation to practice the instant composition without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

7. Applicant's arguments filed 07/28/2005 have been fully considered but they are not persuasive. Applicants traverse the rejection of claims 22-28 under 35 U.S.C. 112 first paragraph by arguing that hot melt acrylic adhesive comprising diiodomethyl-p-tolylsulfone is disclosed as the best mode of practicing the invention. It is also clear, however, that the specification does not foreclose other antimicrobial agents. This particular antimicrobial agent is one of a number of antimicrobial agents capable of functioning in the invention. The specification is replete with terminology characterizing this agent as "preferred" and discussed only by way of "example". It is submitted then that the particular antimicrobial agent disclosed and discussed is not exclusive.

In response to the above argument, the examiner is pointing out to the specification page 7, lines 22-23 of the present disclosure where applicants state that "the antimicrobial agent utilized is diiodomethyl-p-tolylsulfone"; page 9, lines 6-7 applicants state that "at which point the comprising diiodomethyl-p-tolylsulfone is added"; page 12, lines 5-12 applicants state that "Applicants have found that the addition of diiodomethyl-p-tolylsulfone to the above adhesive composition results in an effective antimicrobial adhesive which retains desirable properties during use and application at 275 F to about 350 F. A preferred loading of antimicrobial agent to the adhesive is in the range of about 0.1% to about 2% by weight. A preferred loading is

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about 0.2% by weight to about 0.6% by weight of diiodomethyl-p-tolylsulfone to adhesive". Furthermore, applicants have only tested the antimicrobial effect of hot melt acrylic adhesive containing diiodomethyl-p-tolylsulfone and not any other antimicrobial agents. Therefore, from applicants' disclosure it is clear that only diiodomethyl-p-tolylsulfone has been used in practicing the present invention and it is added at a specific temperature that may not be tolerated or suitable to other antimicrobial agents, and also the specific ranges of diiodomethyl-p-tolylsulfone may not be suitable to other antimicrobial agents. It is not obvious from the disclosure of diiodomethyl-p-tolylsulfone dispersed in hot melt acrylic adhesive if the other antimicrobial agent will work and will stand the high temperature of the hot melt. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724. The present specification does not mention any antimicrobial agent that is suitable to be dispersed in the hot melt adhesives, other than diiodomethyl-p-tolylsulfone. Therefore, the examiner maintains

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her position that specification has enabled diiodomethyl-p-tolylsulfone, but not any other antimicrobial agents.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
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